

REMARKS

Claims 24-29 are pending in this case. Claims 24, 25, and 26 are amended herein.

Applicant acknowledges that this application properly is being treated as a Request for Continued Examination rather than a Continuing Prosecution Application, and appreciates such handling by the Parent Office.

Applicant also acknowledges that the Examiner and Attorney for Applicant, Mr. Joseph Fischer, conducted a brief telephone interview on August 20, 2003 to discuss the reasoning for Applicant's position that the amendment proposed by the Examiner was not needed and the terms suggested were not clearly supported in the specification (as was the term "modulates"). No agreement was reached. Accordingly, Applicant provides the arguments for its position in this response/amendment, which the Examiner assured Mr. Fischer will be reviewed by, at a minimum, the Examiner's SPE.

Rejections under 35 U.S.C. 112

Claims 24-29 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, the Examiner has stated that the word "modulates" in claims 24-26 is indefinite "... as a compound can not (sic) increase and decrease the sodium channel simultaneously." The Examiner has indicated that correction by the "insertion of - - a ligand that either increases or decreases - - will obviate the rejection in base claims 24-26."

Applicant has considered this suggested amendment but believes that the amendment suggested by the Examiner is not necessary because:

- 1) the term "modulates" is clearly and sufficiently defined in the specification such that use of this term in claims 24-26 does not render the claims indefinite;
- 2) the Examiner's suggested amendment may be construed, now or at a later time, to have narrowed the scope of the claim; and
- 3) the Examiner's suggested amendment arguably makes the claims less definite.

These point are discussed in greater detail below:

1. The term "modulates" is clearly and sufficiently defined in the specification such that use of this term in claims 24-26 does not render the claims indefinite

The following is quoted exactly from the specification, starting at page 16, line 27, and going to page 17, line 2:

The novel Drosophila voltage-activated channel sodium channel of the present invention is suitable for use in an assay procedure for the identification of compounds which modulate sodium channel activity. Modulating sodium channel activity, as described herein includes the inhibition or activation of the channel and also includes directly or indirectly affecting the normal regulation of the sodium channel activity. Compounds which modulate the sodium channel activity include agonists, antagonists and compounds which directly or indirectly affect regulation of the sodium channel activity.

One of ordinary skill reasonably reading the phrase "... identifying a ligand that modulates ...," which is found in claims 24-24, will comprehend, having understood the above quoted language, that the ligand with which the first host cell is contacted in step (c) will, in relation to comparison with a "control" cell in step (d), exhibit either a lesser or a greater voltage-activated current that corresponds to "... inhibition or activation of the channel ...". It is axiomatic, and clearly within the grasp of one of ordinary skill in the art, that both will not occur simultaneously. Further, one conducting the method of the test, with sufficient replications, will appreciate whether a ligand is modulating in an inhibitory manner or in an activating manner. Based on well-known statistical methods, if, when sufficient replications are conducted and the data is equivocal (some results showing activation, others showing inhibition), the likely conclusion is that there is no significant difference as to the control and the ligand simply does not act as a modulator. This is one of three possible results – not a modulator, a positive modulator, a negative modulator – under specified test conditions. Such 'equivocal' compound would not be identified as a "ligand that modulates ..." and the researcher could move on to evaluate other ligands.

When there is a meaningful activation of the channel by a ligand, which preferably is statistically significant, this will be interpreted as an activating type of modulation. Any belief that such ligand at such test conditions can, at the same time, also exhibit an inhibitory modulation just is

not consistent with basic laws of logic. (Similar logic applies to a ligand demonstrated to have inhibitory modulating activity.) There is no suggestion the use of the term "modulates," either from general use or as more clearly defined in the specification as quoted above, can be taken to describe a single ligand that operates to both increase and decrease a particular effect simultaneously. Thus, the term should not reasonably be viewed as indefinite.

In summary, the term "modulates" in the claims efficiently expresses what the Examiner wants the claim to state, is amply supported by the specification, and does not in any way render the claim indefinite. Therefore, based on this argument alone, it is respectfully requested that the indefiniteness rejection with regard to use of the word "modulating" be reconsidered and withdrawn.

Further, to make claim 24-26 even more clear and even more clearly consistent with the above-quoted language, each of these claims are amended herein to add the words – activity of – between "modulates" and "a Drosophila membrane . . .". Without this amendment, one of ordinary skill in the art understands the meaning and scope of the claims. With this amendment, the meaning and scope of the claims comes in even yet more clear focus. By this amendment no new matter is added, and the amendment does not in any way narrow claims 24-26.

2. The Examiner's suggested amendment may be construed, now or at a later time, to have narrowed the scope of the claim.

A later alleged infringer will take every opportunity to assault the scope and validity of any claim of which it is accused of infringing. The term "modulates" is clearly and broadly defined in the specification, per the above-quoted language, to include activation and inhibition, whether direct or indirect, and to explicitly include "... agonists, antagonists and compounds which directly or indirectly affect regulation of the sodium channel activity." The same cannot be stated of the suggested substituted phrase – a ligand that either increases or decreases - -. The Examiner has not pointed to language in the specification that provides equivalent breadth to his suggested terms that are clearly associated with the term "modulates." Applicant cannot be assured that a later fact finder will conclude that, by making this substitution, something was meant to be eliminated from the clearly broad meaning of the term "modulates." Thus, in addition to

Applicant's belief that no fundamental basis exists to make the amendment suggested by the Examiner, Applicant believes that the risk of a later adverse interpretation of claim breadth strongly mitigates against amendment to comply with the Examiner's suggested language.

3. The Examiner's suggested amendment does not make the claims more definite.

As discussed above, the term "modulates" is well defined in the specification so its use in claims 24-26 is clear and definite. One skilled in the art will not confuse the matter raised by the Examiner. That is, a researcher will not believe that the method pertains to identifying a ligand that, at a particular concentration under a particular set of test conditions, simultaneously will activate and inhibit the channel in the cell.

Amending these claims to the Examiner's suggested language may well render these claims less definite. For example, neither "increases" nor "decreases" have an inherent reference point; they lack a sense of what testing must be done to achieve the desired result discussed in the specification. Does a method claim practiced one time with the Examiner's suggested language identify a ligand that increases channel activity? If yes, then what result is achieved if the next test shows a negative effect? Is this ligand then a ligand that both increases and decreases channel activity? This, ironically, goes against the Examiner's stated purpose of reducing indefiniteness.

In contrast, the term "modulates," by virtue of its use in the art and its definition in the specification, does not fall prey to such extreme construction that might be applied to "increasing" and "decreasing." It is implicit that a ligand that modulates will have, under specified test conditions, a consistent effect, whether positive or negative as to the system, structure or pathway being used in the testing (in this case a *Drosophila* membrane sodium channel).

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Docket No.: 19338CDCPA2
Serial No.: 08/554,424

SUMMARY

For one or any combinations of the reasoning provided above, Applicant believes the rejection for indefiniteness should be withdrawn. Applicant also believes that the claims are in condition for allowance, and respectfully seeks allowance in the next Office communication.

Respectfully Submitted,

By


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Date: August 20, 2003

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